



ASX/Media Release

Bone Medical receives positive FDA feedback on CaPTHymone™

24 February 2009: Bone Medical Limited (ASX:BNE) today announced that it has had discussions with the FDA on the US regulatory process for CaPTHymone™, Bone's oral Parathyroid Hormone product.

Bone's Chairman, Leif Helth Jensen said "We are very pleased with the outcome of our discussions as we have largely had our plans for product development and regulatory strategy for CaPTHymone™ confirmed."

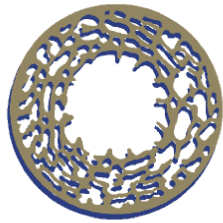
"Our next clinical step is to enter a Phase IIb study where the primary end point will be lumbar spine Bone Mineral Density (BMD) and the secondary end point will be the bio maker P1NP. This study is likely to take 6 months and involve an estimated 150 patients."

"Assuming this trial meets its clinical endpoint, the next step will be a pivotal Phase III non-inferiority study of 12 months duration, involving an estimated 400 patients, which will be sufficient for registration purposes under rule 505(b)(2)." continued Leif Helth Jensen.

The FDA also wants Bone to document that CaPTHymone™'s pharmacokinetics are similar to that of Forteo's (Lilly's injectable PTH product), a benchmark Bone is comfortable it can meet.

Bone's Chief Scientific Officer, Dr Roger New said "For the first time Bone now knows exactly what the FDA will need documented. Based on previous clinical work carried out with CaPTHymone™ we are confident that we will be able to meet these requirements. We are also pleased that the FDA has recognised the product development and regulatory strategy which Bone initiated 2-3 years ago. The challenges set by the FDA for CaPTHymone™, in comparison with new chemical entity drugs, are in general less expensive, and with the right level of funding can be finalised over the next few years."

END



Bone Medical

Enquiries:

Leif Helth Jensen
Chairman
Mobile: +45 4052 0787

Rudi Michelson
Monsoon Communications
+61 3 9620 3333

Australian Office: +61 8 9355 5123

Troels Jordansen
Managing Director
Mobile: + 44 79 1713 0019

Or visit: www.bonemedical.com

About Bone Medical Limited

Bone Medical Limited is an international biopharmaceutical development company positioned to exploit the growing market in the treatment of bone disease particularly in osteoporosis and arthritis. Bone has a portfolio of biopharmaceutical development projects for the treatment of bone disease including,

Osteoporosis

- · Capsitonin™ oral calcitonin
- · CaPTHymone™ oral parathyroid hormone
- · bone cell regulators BN005 & BN008

Arthritis

- · TNF regulators BN006
- · joint protection & collagen tolerance BN007